REMARKS

Claims 63-65 and 67-78 are pending. Claim 66 was previously cancelled. Claim 69 is cancelled herein. Accordingly, claims 63-65, 67, 68, and 70-78 are at issue.

Claim 78 stands rejected under 35 U.S.C. § 112 ¶ 1 as failing to comply with the written description requirement. Claim 78 is amended herein to obviate the rejection.

Claims 63-65 and 67-73 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent App. Pub. No. 2004/0019353 to Freid et al. in view of U.S. Patent No. 2,376,768 to Glumer. Claim 74 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Freid et al. in view of Glumer and further in view of U.S. Patent No. 6,454,769 to Wagner et al. Claims 75-77 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Freid et al. in view of U.S. Patent No. 5,626,449 to McKinlay.

The rejections, as they may apply to the claims presented herein, are respectfully traversed.

Claim 63 is directed to a device for stabilization of adjacent vertebrae including a bone plate, a plurality of bores in the bone plate, and a bone anchor configured for extending through one of the bores. Claim 63, as amended, recites that the bone anchor has a head with a spherical outer surface and a shank depending from the head. Further, claim 63 recites a pair of spaced, flat portions of the one bore that extend substantially parallel to one another. Claim 63, as amended, calls for a rotary anchor lock collar member extending about a central axis for being rotatably received in the one bore. Amended claim 63 further calls for a curved inner surface of the rotary anchor lock collar member adapted to engage the spherical outer surface of the head of the bone anchor to permit the bone anchor to be rotationally driven through the one bore along one of a plurality of different driving axes that are transverse to the central axis and into a vertebral bone. The rotary anchor lock collar member has a lower portion with a split-ring construction with spaced circumferential ends that are spaced apart from one another by a gap therebetween. The anchor lock lower portion has larger and smaller dimensions with respective axes that extend through a center of the rotary anchor lock collar member substantially

orthogonal to each other. Claim 63 calls for cooperating inner and outer surfaces of the one bore flat portions and the anchor lock lower portion, respectively, which cause the facing ends to shift toward each other with approximately ninety degrees of rotation of the rotary anchor lock collar member after the bone anchor has been driven through the one bore and into a vertebral bone. Further, rotation of the rotary anchor collar member is independent from the rotational driving of the bone anchor such that rotation of the rotary anchor lock collar member from an open, bone anchor receiving configuration to a clamped, bone anchor locking configuration causes the facing ends to shift toward each other to reduce the size of the gap therebetween. In this manner, a bone anchor extending through the one bore and the rotary anchor lock collar member therein is locked against polyaxial movement relative to the bone plate and the rotary anchor lock collar member. None of the relied upon art, either alone or in combination, discloses or suggests a rotary anchor lock collar member extending about a central axis and having a curved inner surface adapted to engage a spherical outer surface of a head of a bone anchor to permit the bone anchor to be rotationally driven along one of a plurality of different driving axes that are transverse to the central axis, as recited by amended claim 63. Nor do the cited references disclose or suggest a rotary anchor lock collar member having a clamped, bone anchor locking configuration wherein the bone anchor extending through the rotary anchor lock collar member is locked against polyaxial movement relative to the bone plate and the rotary anchor lock collar member, as recited by amended claim 63.

In the Action, it is asserted that it would be obvious to modify the retainer 46 of Freid et al. to include outer surfaces of a washer 5 of Glumer to provide "a mechanism for immobilizing the bone screw, anchor lock, and plate relative to one another once they are in the desired orientation." Office Action, page 8. In the first instance, there is no motivation to modify the retainer 46 as asserted in the Action because Freid et al. rely upon a rotation-independent approach to keep an anchor 182 within a bore 40. Specifically, Freid et al. teach projections 50 that extend radially inward over an engagement section 192 of the anchor 182 to inhibit removal of the anchor 182 from the retainer 46. Thus, modifying the retainer 46 to hold the anchor 182 by constricting thereabout would render the only mechanism taught by Freid et al. for retaining

the anchor 182 within the bore 40, i.e., the retainer projections 50 and the anchor section 192, completely superfluous.

Further, the applied references also fail to teach the recited rotary anchor lock collar member that permits a bone anchor to be driven along a plurality of different driving axes relative to a central axis of the rotary anchor lock collar member. More particularly, the applied references fail to provide such functionality via engagement between the recited curved inner surface of the rotary anchor locking collar member and the spherical outer surface of the bone anchor head, which are nowhere shown by the references. Instead, Freid et al. teach that the retainer 46 has an inclined surface 208 that receives a tapered section 190 of the anchor 182 along a single axial path (see FIGS. 23 and 25). The retainer 46 has a portion that fits into a bore recess 48 and is thinner than a height of the recess 48. This difference in height permits the retainer 46 to rock within the recess which, in turn, allows angulation of the fastener 182 (see paragraph [0127]). Thus, whereas Freid et al. disclose a fixed relation between the anchor 182 and the retainer 46, and relative movement between the retainer 46 and the bone plate 30, the rotary anchor lock collar member of claim 63 utilizes a curved inner surface to engage a spherical outer head surface of a bone anchor to permit the bone anchor to be driven along one of a plurality of different driving axis relative to the anchor lock collar member. Glumer fails to cure the shortcomings of Freid et al., as Glumer does not contemplate any sort of polyaxial orientation of the bolt relative to the nut 2. Instead, Glumer discloses a threaded interior surface 15 of the washer 5 that engages a threaded shank of a bolt (see FIGS. 6, 9, 10). Thus, it is respectfully submitted that the applied references, either alone or in combination, do not disclose or suggest the structural or functional aspects of the device of claim 63.

Moreover, even if the retainer 46 of Freid et al. were modified to include the outer surfaces of the washer 5 of Glumer, the resulting device would still lack a clamped, bone anchor locking configuration wherein a bone anchor extending through a bore is locked against polyaxial movement relative to the bone plate and the rotary anchor lock collar member, as recited by amended claim 63. Instead, as discussed above, Freid et al. teach that the retainer 46 has a portion that fits into a bore recess 48 and is thinner than a height of the bore recess 48 to

permit the retainer 46 to rock within the recess 48 and allow angulation of the fastener 182. As such, even if the retainer 46 were to constrict about the fastener 182, the retainer 46 and the fastener 182 could still move relative to the bone plate due to the difference in height between the retainer 46 and the recess 48 necessary to accommodate polyaxial insertion of the fastener 182. Accordingly, it is respectfully submitted that amended claim 63, and claims 64, 65, 67, 68, and 70 which depend cognately therefrom, are allowable over the applied references.

Claim 71 is directed to a device for stabilization of adjacent vertebrae, the device including a bone plate with a plurality of bores. At least one of the bores is a dynamized bore having an elongate configuration to allow a bone screw extending therethrough to shift relative to the bone plate. Further, the dynamized bore has a pair of opposed flat portions which extend along the length of the bore. Claim 71 calls for a screw lock member configured to be rotatably received in the dynamized bore for being rotated between a screw receiving unlocked configuration and a screw locking configuration. Claim 71, as amended, recites a pair of diametrically opposed outer flats of the screw lock member which have a planar configuration, the flats facing radially outward from the screw lock member and extending parallel to one another. Claim 71 specifies that rotation of the screw lock member to the screw locking configuration brings the flats into confronting relation with the opposed bore flat portions. The flats of the screw lock member are configured to slide along the bore flat portions to permit translation of the bone screw and the screw lock member in the dynamized bore. Claim 71, as amended, recites that the confronting engagement of the flats of the screw lock member against the flat portions of the dynamized bore avoids turning of the screw lock member in the dynamized bore as the screw lock member slides along the bore flat portions to keep the screw lock member in the screw locking configuration for resisting back out of the bone screw from the bore. The applied references, either alone or in combination, do not disclose or suggest a screw lock member having a pair of diametrically opposed outer flats facing radially outward and extending generally parallel to one another. Nor do the applied references disclose or suggest a confronting engagement of the outer flats of the screw lock member against a pair of opposed

flat portions of a dynamized bore which keeps the screw lock member in a screw locking configuration, as recited by amended claim 71.

In the Action, it is acknowledged that Freid et al. fail to disclose an anchor lock lower portion including two substantially flat surfaces that are diametrically opposed to one another, wherein rotation of the screw lock member brings the flats into confronting relation with opposed bore flat portions. Office Action, page 9. For this, Glumer is relied upon. Glumer discloses a non-loosening nut 1 having a circular groove 2 for receiving a washer 5 (see FIGS. 1 and 5; col. 2, lines 38-39). When the nut 1 is tightened onto a bolt, relative loosing movement between the nut 1 and bolt (rotation of nut 1 in counter clockwise direction as viewed in FIG. 1) causes the nut 1 to cam excentric surfaces 3 of the groove 2 against curved surfaces 8 of the washer 5 to reduce reduce the diameter of the washer 5. Further, Glumer describes the rounded nature of the washer outer surfaces:

> Washer 5 is provided on its convex wall 7 with one or more excentric, curved surfaces 8 of corresponding construction to the groove 2 in nut 1 . . . .

Col. 3, lines 6-9. FIG. 5 of Glumer is reproduced to the right, and illustrates the curved surfaces 8 of the washer 5. Thus, whereas Glumer teaches that curved surfaces 8 of washer 5 cam against a circular groove 2 of nut 1, amended claim 71 calls for a pair of substantially planar flats of the screw lock member for being rotated into confronting engagement with opposed flat portions of a bore.

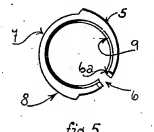

Fig.5.

The recited outer flats of the screw lock member provide resistance to turning of the screw lock member away from a screw locking configuration and permit the screw lock to slide along flat portions of an elongate bore. In the Action, it is asserted that it would be obvious to modify the retainer 46 of Freid et al. to include outer surfaces of a washer 5 of Glumer to "provide[] a mechanism for immobilizing the bone screw, anchor lock, and plate relative to one another once they are in the desired orientation." Office Action, page 12 (emphasis added). This alleged motivation, however, is directly contrary to providing a screw lock member that slides

along a pair of opposed flats of an elongated bore. Thus, even if a person of ordinary skill in the art were attempting to produce the device of amended claim 71, they would have no reason to combine the retainer 46 of Freid et al. with the washer 5 of Glumer as asserted in the Action. Accordingly, it is respectfully submitted that amended claim 71, and claims 72-74 and 78 which depend cognately therefrom, are allowable over the applied references.

Claim 75 is directed to a bone plate system for securing a plurality of bones including a bone plate and a plurality of bores extending through the plate which receive bone anchors for securing the plate to the plurality of bones. Claim 75 calls for a channel of one of the bores, the channel being located between top and bottom surfaces of the plate and having upper and lower surfaces extending radially outward from the bore. Claim 75, as amended, calls for a split ring locking collar configured for being rotatably received in the one bore. The locking collar has a radially outer step portion with a thicker portion and a thinner portion extending about the circumference of the step portion. The thicker portion is continuous about the circumference of the step portion, and the thinner portion is interrupted by the split in the split ring locking collar. Further, claim 75 recites an upwardly facing cam surface extending between the thicker and thinner portions of the locking collar step portion configured for camming against the channel upper surface so that rotation of the locking collar toward a locked configuration thereof brings the locking collar cam surface into engagement with the channel upper surface which causes a tight wedge fit of the step portion thicker portion in the channel. The applied references, either alone or in combination, do not disclose or suggest a split ring locking collar having a radially outer step portion with a thicker portion being continuous about the circumference and a thinner portion being interrupted by the split in the split ring, as recited by amended claim 75.

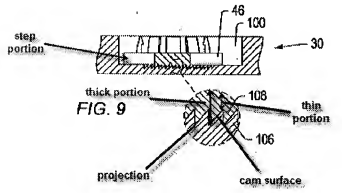

FIG. 9

Instead, Freid et al. disclose a retainer 46 having serrations 108 that engage serrations 106 on a lower surface of an opening 100 to restrict longitudinal movement of the retainer 46 in the opening 100 (see paragraph [0097]). In the Action,

the incremental sections of the retainer 46 are interpreted as being thicker and thinner portions of a locking collar step portion with a cam surface disposed therebetween (see figure from Office Action reproduced above). The Action acknowledges, however, that Freid et al. do not disclose that the cam surface is used in a rotational manner, and that the cam surface is on an upper surface of the retainer 46. Office Action, page 14. The Action relies upon McKinley as evidence that these aspects would be obvious.

However, even if the retainer 46 of Freid et al. were modified as asserted in the Action, the resulting device would not provide a primary utility of the device of claim 75. More specifically, rotating the split ring locking collar of claim 75 to a locked configuration produces a tight wedge fit of the step portion thicker portion in the channel to resist reverse rotation back toward an unlocked configuration of the collar in the bore. Freid et al., by contrast, teach such a large number of serrations that if the serrations 108 were formed on the top of the retainer 46, the retainer 46 could not rotate within the bore 100. Even if the serrations 106, 108 of Freid et al. were modified to resemble the cam surfaces 34, 26 of McKinlay, the serrations would still restrict all rotational movement of the retainer 46 because the serrations would be disposed around the entirety of the circumference of the retainer 46. Claim 75, by contrast, describes a two-part step portion that permits a limited amount of rotation of the collar before thicker portion of the step portion is wedged within the channel. Neither Freid et al. nor McKinlay disclose or suggest such operability. Accordingly, it is respectfully submitted that claim 75, and claims 76 and 77 which depend therefrom, are allowable over the applied references.

Based on the foregoing, reconsideration and allowance of claims 63-65, 67-68, and 70-78 are respectfully requested. The Commissioner is hereby authorized to charge any additional fees which may be required in this matter, or to credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNNERY

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/Jonathan H. Urbanek/
Jonathan H. Urbanek
Registration No. 60,686

FITCH, EVEN, TABIN & FLANNERY
120 South LaSalle Street - Suite 1600
Chicago, Illinois 60603-3406
Telephone: (312) 577-7000
Facsimile: (312) 577-7007
562110